

### REMARKS

Applicants respectfully request reconsideration of the rejections set forth in the Final Office Action mailed on May 14, 2003. Claim 52 has been cancelled herein. Claims 40-43, 45, and 51 are pending. All claims have been rejected.

This amendment is to expedite prosecution and should not be construed as acquiescence in any ground of rejection. Applicants reserve the right to prosecute the originally filed claims in the future.

#### *Rejections under 35 U.S.C. §112, 1<sup>st</sup> Paragraph*

##### *Written Description*

Claim 52 has been rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. Applicants respectfully disagree. However, as the claim has been cancelled herein, the rejection is moot.

##### *Enablement*

The claims have been rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for alleged lack of enablement. Specifically, the Examiner maintains that the specification lacks guidance, direction and examples for deriving the morphological values and/or their degrees of presence. Applicants respectfully traverse this rejection.

Applicants acknowledge with appreciation the Examiner's clarification of this rejection. Apparently, the Office continues to be concerned about the phrase related to "code for producing a statistical profile of said manipulated cells by combining the morphological values or degrees of presence of said morphological values in said plurality of different cell lines whereby a statistical profile of said manipulated cells is produced . . . ." The Office indicates that that the only exemplification of such code is at pages 34-45 of the Specification. The Office further maintains that the claims embrace more than what is taught in the original disclosure because no other methods (i.e., code) are disclosed.

Applicants disagree and respectfully maintain that the claims are enabled according to the standards set forth in the M.P.E.P. and caselaw. As noted in Applicant's prior response, the

present invention provides *computer software* for mapping a manipulation of cells based upon a morphological characteristic.

Figures 4 and 5 depict various morphologies (such as apoptotic, abnormal mitotic, normal interphase, and normal mitotic) in a cell population responsive to drug concentration. These cellular morphologies or attributes are reflected by the corresponding morphological value and associated degree of presence. Morphological values or parameter, as claimed herein, can be a cell count, an area, a perimeter, a length, a breadth, a fiber length, a fiber breadth, a shape factor, an elliptical form factor, an inner radius, an outer radius, a mean radius, an equivalent radius, an equivalent sphere volume, an equivalent prolate volume, an equivalent oblate volume, an equivalent sphere surface area, an average gray value, a total gray value, and an optical density. The associated degree of presence is the mathematical value of the morphological parameter. For example, the morphological value may be area of between 6000 and 19,000 (see, Specification at page 30). The associated degree of presence for this morphological parameter would be 917 (i.e., there were 917 objects that had an area between 6000 and 19,000).

In addition, these morphological values can be *mathematically combined*. For example, the Specification at page 30 provides an example of the combining of area and average gray value. Thus, the morphological values would be area of between 6000 and 19,000 and an average gray value of >60. The associated degree of presence would be 116 (i.e., 116 of the objects being analyzed had an average gray value of >60 and an area of between 6000 and 19,000). A scatter plot of area versus average gray value was also produced. In addition, the Specification at pages 36-45 provides pseudocode for the commercial program AnalyseDNA.m program which can be used to capture and manipulate various morphological values.

As noted in M.P.E.P. § 2106.02:

While no specific universally applicable rule exists for recognizing an insufficiently disclosed application involving computer programs, an examining guideline to generally follow is to challenge the sufficiency of such disclosures *which fail to include either the computer program itself or a reasonably detailed flowchart which delineates the sequence of operations the program must perform.*

The present application includes both an exemplary computer program (as noted by the Examiner) and a detailed flowchart. See, e.g., Figs. 1, and 2A-2J. The specification also includes a functional description of the method as well as other examples as described above.

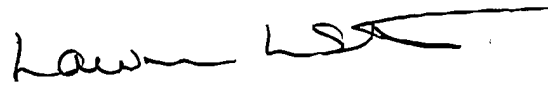
Finally, the Federal Circuit held in *Fonar v. General Electric*, 107 F.3d 1543 (CAFC 1997), that source code and flow charts are not required where the software functions are

disclosed sufficiently. "As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. . . . [F]low charts or source code listings are not a requirement for adequately disclosing the functions of software." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (citations omitted).

Applicants believe that a programmer skilled in the art could readily create code to capture morphological values, assign their associated degrees of presence, produce a statistical profile by combining these values, and map the effect of the manipulation based upon the statistical profile. Applicants respectfully submit that the claims are enabled under the standard enumerated under *Fonar* and the M.P.E.P. and request withdrawal of this rejection.

Applicants believe that the claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

Respectfully submitted,  
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